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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/280,270 03/29/99 MACEVICZ

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EXAMINER

S 5525-0015.21

ART UNIT	PAPER NUMBER
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FILE
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/280,270

Applicant(s)
Macevicz

Examiner
Frank Lu

Group Art Unit
1655



☒ Responsive to communication(s) filed on May 16, 200

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 20-31 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 20-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Drawings

1. The drawings remain objected to for reasons as stated on FORM PTO-948 (Rev. 8-98) which was attached to Paper NO: 5. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-25 are rejected as vague and indefinite over the phrase “substantially the same free energy of duplex formation” in claim 20 because it is unclear what means “substantially the same free energy of duplex formation”. For example, does “substantially the same free energy of duplex formation” mean that the different-sequence, single-stranded oligonucleotide with the length from 3 nucleotides to 30 nucleotides (see claim 25) have the same free energy of duplex

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formation or does “substantially the same free energy of duplex formation” mean something else? This rejection can be overcome by clarifying the meaning of “substantially the same free energy of duplex formation”.

4. Claims 26-31 are rejected as vague and indefinite over the phrase “ the same stringency class” in claim 26 because it is unclear what means “the same stringency class”. For example, does “the same stringency class” mean that any kind of nucleotides with the length of 8-12 base pair is from the same stringency class or “the same stringency class” means something else? This rejection can be overcome by clarifying the meaning of “the same stringency class”.

Claim Rejections - 35 USC § 102

5. Upon review of applicants’ amendments and remarks, the rejection in the first office action under 35 U. S. C 102(e) has been withdrawn by the examiner.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 20, 21, 26, 28, and 29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pease *et al.*, (Proc. Natl. Acad. Sci. USA, 91, 5022-5026, 1994).

Pease *et al.*, teach light-generated oligonucleotide arrays for rapid DNA sequence analysis. In this study, 256 single-stranded, different octanucleotides which have different annealing temperatures were immobilized on a microchip. The hybridization pattern of fluorescently labeled oligonucleotide target was then detected by epifluorescence microscope (page 5022, abstract). This prior meets the limitation of the claim.

In the alternative, an assay for oligonucleotide array is performed in a single hybridization temperature so that the most of oligonucleotides in an array can be efficiently used (page 5026, Figure 5). Note that, in the second paragraph of page 16 of the specification, the applicant states "probes whose perfectly matched duplexes with complementary sequences have similar stability or free energy of binding. Such subsets of oligonucleotide probes having similar duplex stability are referred to herein as "stringency class" of oligonucleotide probe". It is unclear how many percent of base match can be considered as "perfectly matched" and what kind of oligonucleotide probes can be considered as "having similar duplex stability". For example, (1) in claim 20, the oligonucleotides have length up to 12 nucleotides while in claim 25, an initializing oligonucleotide has a length of from 20 to 30 nucleotides, do the different-sequence, single-stranded

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oligonucleotide with the length from 3 nucleotides to 30 nucleotides have the same free energy of duplex formation? (2) is any kind of nucleotides with the length of 8-12 base pair from "the same stringency class"? Without clearly defining the meaning of "perfectly matched" and "similar duplex stability" in the specification, the phrase "substantially the same free energy of duplex formation" which encompasses claims 20 and 21 and "the same stringency class" which encompasses claims 26, 28, and 29 will be considered as vague and indefinite. Therefore, the examiner will consider that 256 single-stranded, different octanucleotides immobilized on a microchip (see the reference from Pease *et al.*) have or suggest "substantially the same free energy of duplex formation" and are from or suggest "the same stringency class". Therefore, in the absence of convincing evidence to the contrary the claimed invention as whole is considered prima facie obvious, if not anticipated by the prior art of record. . The rejection will remain.

Response to Arguments

Applicant's arguments "there is no teaching or suggestion to employ subsets of oligonucleotides defined, by their free energy of duplex formation, as stringency classes, as in the present claims" filed on 5/16/2000 on Paper No: 7 have been fully considered but they are not persuasive to withdraw the rejection. The examiner noticed that, in the second paragraph of page 16 of the specification, the applicant states "probes whose perfectly matched duplexes with complementary sequences have similar stability or free energy of binding. Such subsets of oligonucleotide probes having similar duplex stability are referred to herein as "stringency class" of oligonucleotide probe". It is unclear how many percent of base match can be considered as

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“perfectly matched ” and what kind of oligonucleotide probes can be considered as “having similar duplex stability”. For example, (1) in claim 20, the oligonucleotides have length up to 12 nucleotides while in claim 25, an initializing oligonucleotide has a length of from 20 to 30 nucleotides, do the different-sequence, single-stranded oligonucleotide with the length from 3 nucleotides to 30 nucleotides have the same free energy of duplex formation? (2) is any kind of nucleotides with the length of 8-12 base pair from “the same stringency class”? Without clearly defining the meaning of “perfectly matched ” and “similar duplex stability” in the specification, the phrase “substantially the same free energy of duplex formation” and “ the same stringency class” will be considered as vague and indefinite. Therefore, the examiner will considered that 256 single-stranded, different octanucleotides immobilized on a microchip (see the reference from Pease *et al.*) have or suggest “substantially the same free energy of duplex formation” and are from or suggest “the same stringency class”. The rejection will remain.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

10. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,750,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim 1 in this instant application and claim 1 of U.S. Patent No. 5,750,341 are directed to a method for identifying a sequence of nucleotides in a polynucleotide. Note that claim 1 in this instant application is much broader and has less method steps than claim 1 of U.S. Patent No. 5,750,341.

Conclusion

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

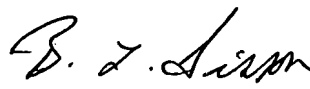
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
August 14, 2000


BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP 1800/1650
8/14/00